UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,904	02/20/2002	Yonghong Yang		3952

41158 7590 11/15/2004	EXAMINER	
LYNN E. MURRY	ZEMAN, MARY K	
424 WEST PATRICIA LNAE		
FAYETTEVILLE, AR 72703	ART UNIT	PAPER NUMBER
	1631	

DATE MAILED: 11/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _04 August 2004_.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1-8 and 23-36_ is/are pending in the application.

  4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-8 and 23-36_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _20 February 2002_ is/are: a)☒ accepted or b)☐ objected to by the Examiner.

  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

  a)☐ All b)☐ Some * c)☐ None of:

   1.☐ Certified copies of the priority documents have been received.

   2.☐ Certified copies of the priority documents have been received in Application No. _____.

   3.☐ Copies of the certified copies of the priority documents have been received in this National Stage
     application from the International Bureau (PCT Rule 17.2(a)).

  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
   Paper No(s)/Mail Date ___8/02___

4) ☐ Interview Summary (PTO-413)
   Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of Group I, claims 1-8 and new claims 23-36 in the reply filed on 8/4/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's comments regarding possible rejoinder have been considered. Applicant has CANCELED claims 9-22 (drawn to methods).

Priority

Applicant's claim to priority to two separate provisional applications is acknowledged.

Information Disclosure Statement

The IDS filed 8/23/2002 has been entered and considered. An initialed copy of the PTO-1449 is included with this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 23-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 1 (and claims 2-8, 23-36 which depend thereon), the word "means" is preceded by the word(s) "data storage" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) preceding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967). The limitations following the recitation "data storage means" do not further limit the storage means, but the data contained therein. This data is generally considered to be non-functional descriptive data which has no specific effect or imposes no specific structural limitations on the apparatus which stores it.

Claim 2 does not further limit the apparatus or system of claim 1, as the limitations regarding the type of data do not further limit the "storage means" itself.

In claims 3 and 4, it is unclear if the list of functions is a pseudo code of all functions that must be performed and in that order? Or can one or more functions be performed in differing order? Are these merely capabilities, or an indication of a specific program?

Claim 5 is confusing, as the data should be entered into the system using the data entry means. It appears Applicant is attempting to limit the type or form of data to be entered, but that is not what the limitation recites.

Claim 6 is a process limitation, and not a further structural limitation of the system. It is essentially an intended use for the display means. It provides no structural limitation as to what the display means comprises.

In claim 7, it is unclear if the list of functions is a pseudo code of all functions that must be performed and in that order? Or can one or more functions be performed in differing order? Are these merely capabilities, or an indication of a specific program?

It is unclear in claim 8 what data is used to run the dynamic programming algorithm. What data from the data storage means is to be utilized? Further in claim 8, the alignment of the "where D>0" is not clear- is it intended to go <u>before</u> equation 2 (w (a_{ik}, a_{ji})=...) or in the middle of it? It is unclear how step (c) is related to the results of step (b), and the term "using traceback" is not a positive active method step clearly identifying the step to be performed or data manipulation to be made.

In claim 23, the term "pair of proteins in the database" lack antecedent basis. The data storage means in claim 1 comprises protein <u>pathways</u>, (and annotated information about the pathway) and not the proteins themselves.

Claim 24 does not further limit the system/ apparatus of claim 3. The limitations of claim 24 are process limitations which do not limit the structure of the system being claimed.

Claim 25 does not further limit the system/ apparatus of claim 7. The limitations of claim 25 are process limitations which do not limit the structure of the system being claimed. It is unclear if Applicant intends these limitations to further limit a program, or the central processing unit. The claim is not presently limited to that interpretation. In claim 25, the abbreviation SCIM should be spelled out at its first instance in the claims for clarity.

In claim 26, the limitations regarding protein sequences in the database lack antecedent basis in claim 1. The data storage means of claim 1 comprises protein <u>pathways</u>, (and annotated

information about the pathway) and not the proteins themselves. Further in claim 26, the abbreviations OS-score should be spelled out at their first instance for clarity.

Claims 27-29, 33, 34 do not further limit the system/ apparatus of claim 3. The limitations of claim 27-29 are process limitations which do not limit the structure of the system being claimed.

Claim 30, (31, 32) does not further limit the system/ apparatus of claim 7. The limitations of claim 30 are process limitations which do not limit the structure of the system being claimed. It is unclear if Applicant intends these limitations to further limit a program, or the central processing unit. The claim is not presently limited to that interpretation.

The limitations of claim 35 do not appear to be clearly related to the system of claim 1. Claim 1 recites specific structural elements, none of which comprise genes, candidate pathways, cellular location, etc. Further, the step of "using" protein interactions fails to specifically point out what data manipulations are to be performed to arrive at a predicted function.

Similarly in claim 36, the step of "applying" a type of programming does not clearly point out how the data of steps a and b result in the prediction of any novel pathway.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 24, 27-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuffner (2000).

The rejected claims are drawn to systems which comprise a data entry means, a display means, a CPU programmed to certain functions, and a data storage means comprising biological pathway information, and annotations thereof. The storage device comprises a relational database comprising a variety of tables. The tables can comprise sequence information about proteins involved in the pathways, interactions, related mRNA, microarray and expression data, genes etc. The CPU is programmed to retrieve, input, and manipulate protein pathway data. The data is entered in a specific format. Applicant is entitled to a priority date of 2/20/2001.

Kuffner (Bioinformatics (2000) Ref 13, PTO-1449) discloses the DMD system. The system of Kuffner et al comprises a data entry means ("information from each data source is extracted and compiled into a PETRI NET." P 825), a means for display (Differential metabolic display which allows comparison of specific systems i.e. organisms, tissues or disease states with the biochemical knowledge contained [in] the currently available databases or for identifying and exhibiting specific differences among two or more systems... p825-826) a programmed CPU (algorithms section, pages 830-832) and data storage means (PETRI net.). The data storage means (the PETRI nets) comprise related tables of information regarding proteins and their interactions. This is a relational database meeting the limitations of claims 1-2. The information contemplated by Kuffner et al to be used in their methods include gene and protein sequence information, annotations, and known interactions with other entities; Chemicals, their names, and known interactions; Microarray data, expression data, data relating to diseases, etc. The CPU can compare sequences, compare presence of proteins in systems, develop pathways and connections between data in the database, etc. A standard representation for known metabolic pathways is used, from standard databases like BRENDA, ENZYME, EMP, MPW, WIT, EcoCyc, HincCyc and KEGG or KEGG/LENZYME. As such, Kuffner meets the limitations of the rejected claims.

Claims 1-7, 24, 27-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakao (1999).

Nakao et al. (1999, Ref 6, PTO-1449) discloses the KEGG system. The system of Nakao et al comprises a data entry means (information about the array experiment and about each spot, p 2), a means for display (Figure 1, Java Applets) a programmed CPU (sections 2.3, 2.4, 3.2,

3.3). The data storage means (the EXPRESSION database) comprise related tables of information regarding proteins and their interactions. This is a relational database meeting the limitations of claims 1-2. The information contemplated by Nakao et al to be used in their methods include gene and protein sequence information, annotations, Microarray data, expression data, data relating to diseases, etc. The CPU can compare sequences, compare presence of proteins in systems, develop pathways and connections between data in the database, etc. (Sections 2.3, 2.4, 3.2, 3.3, discussion) A standard representation for known metabolic pathways is used, KEGG or KEGG/LENZYME entry. As such, Nakao meets the limitations of the rejected claims.

Claims 1, 2, 4, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Seilhamer et al. (US 6,023,659).

Seilhamer et al. (USP 6,023,659) discloses systems which comprise a data entry means, a means for displaying data, and programmable CPU, and a data storage means comprising annotated information about protein pathways (See Figure 2, 4A). The database system of Seilhamer is a relational database system of related tables. (col 2). The tables comprise information about proteins, their sequences, interactions, functions etc. The system can display lists of the tables (col 3) as well as a variety of other information (See figures). The programmed CPU can provide protein sequence analysis and comparisons, and predict functions based on sequence similarity scores. As such, Seilhamer anticipates the rejected claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6,643,634 Koleszar et al.

US 2003/0009295 Markowitz et al.

US 2003/0033126 Lincoln et al.

Us 2002/0194201 Wilbanks et al.

US 2002/0168664 Murray et al..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary K Zeman whose telephone number is (571) 272 0723

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P Woodward can be reached on (571) 272 0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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MARY K. ZEMAN

PRIMARY EXAMINER